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I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 10/23/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE OHIO BOARD OF PHARMACY
(Case Number A-2025-0227)

In The Matter Of:

CryoOH DBA: Cryo Ohio Inc.
3673 Paxton Ave
Cincinnati, OH 45208
Revoked License No. 02-60001584

INTRODUCTION

On August 6, 2025, the Ohio Board of Pharmacy (Board) issued a Summary Suspension/Notice of Opportunity for Hearing (Notice) to CryoOH DBA: Cryo Ohio Inc. (CryoOH) via registered email to CryoOH's email of record with the Board. The Certified Record of Opening confirmed the Notice was delivered and opened on August 6, 2025. Pursuant to Ohio Revised Code Section 119.07, CryoOH had a right to a hearing if requested within thirty days of service. CryoOH failed to request a hearing by the thirtieth and final day. Accordingly, as no hearing was requested, the matter came before the Board under the authority of *Goldman v. State Med. Bd. of Ohio*, 110 Ohio App.3d 124, 129 (10th Dist.1996) on October 7, 2025, before the following members of the Ohio Board of Pharmacy (Board): Jeff Huston, RPh, Presiding; Jason George, RPh, Vice President; Anthony Buchta, Sr., RPh; Mindy Ferris, RPh; T.J. Grimm, RPh; and Leonard Hubert, Public Member.

Absent: Trina Buettner, RPh; Rich Miller, RPh; Tom Whiston, RPh.

CryoOH DBA: Cryo Ohio Inc. did not have a representative present and the entity was not represented by counsel. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Sarah Nash – Board Specialist

Respondent's Witnesses:

1. None

State's Exhibits:

1. Notice Letter
2. Inspection Report
3. Response to Inspection Report
4. Photos taken during inspection
5. Affidavit of Danielle Fisher

Respondent's Exhibits:

A. None

FINDINGS OF FACT

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds the following to be fact:

1. On or about July 23, 2025, a Board Specialist and Board Agent (Board inspectors) conducted an inspection at CryoOH DBA: Cryo Ohio Inc. (CryoOH), located at 3673 Paxton Ave Cincinnati, Ohio. Mary Beth Schell, CryoOH's owner, who is not a licensed healthcare professional, was present and assisted Board Inspectors during the inspection. At the time of the inspection, CryoOH employed the following healthcare professionals: Christopher D. Lawley, DO [Ohio Medical Board license number 34.004502]; Jonathan W. Van Zile, MD [Ohio Medical Board license number 35.053908]; Meghan I. Johnson, CRNA [Ohio Board of Nursing license numbers APRN.CRNA.07268 and RN.274865]; Lindsey France, CRNA [Ohio Board of Nursing license numbers APRN.CRNA.0020548 and RN.505468]; and Erin Sedgwick, RN [Ohio Board of Nursing license number RN.326607].

2. The inspection revealed CryoOH was in possession of illegal dangerous drugs, listed in Allegation 3, purchased from Alpha BioMed and Unboxed Fillers.

    a. Alpha BioMed is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration. Dangerous Drugs purchased from Alpha BioMed are misbranded.

    b. Unboxed Fillers's website states they are a licensed facility in Europe; however, Unboxed Fillers is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration. Dangerous Drugs purchased from Unboxed Fillers are misbranded.

3. CryoOH was in possession of the following illegal drugs during the inspection:

    a. 3 vials of Botox Cosmetic vials with non-English text on the labels

        i. 2 vials were used and 1 vial was partially used

1. Botox is manufactured by Allergan and sold by AbbVie. On or about July 24, 2025, after review of the vials, AbbVie confirmed the vials were manufactured- for and distributed to- Turkey. While the product was authentic, it was not purchased through a legal supply chain and was not approved by the U.S. Food and Drug Administration (FDA). It was illegal in the United States.

b. 2 vials of Dysport with non-English text on the labels

   i. 1 vial was unused vial and 1 vial was partially used

      1. Dysport is manufactured by Ipsen. On or about July 31, 2025, after review of the vials, Ipsen confirmed the vials were diverted product and not purchased from a legal supply chain. The vials were originally distributed to Turkey. The product was authentic; however, it was not approved by the FDA and was illegal to purchase and possess in the United States.

c. 10 vials of injectable products from Alpha BioMed, including:

   i. 5 vials of BPC-157/TB 500 10 mg/10 mg/vial

      1. 4 vials were unused and 1 vial was partially used

   ii. 3 vials of GLOW (GHK-CU/BPC 157/TB 500) 27/5/10 mg/vial

      1. 2 vials were unused and 1 vial was partially used

   iii. 2 vials of NAD+ Biofermented 1000 mg/vial

      1. 1 vial was unused and 1 vial was partially used

4. The inspection conducted on July 23, 2025, resulted in seven warnings requiring written responses and two warnings, including but not limited to:

   a. Purchased dangerous drugs from unlicensed entities.

      i. Board inspectors observed vials of injectable drugs from unlicensed entities, Alpha BioMed and Unboxed Fillers.

      ii. The clinic did not complete a query of the board's online roster prior to purchase of dangerous drugs at wholesale.

   b. Non-controlled dangerous drugs and hypodermics were not maintained under appropriate supervision and control.

i. Dangerous drugs and hypodermics were stored in the clinic's medication room which was accessible by two doors with keypad locks. During the inspection, one door was open to a second room where patients may receive treatment.

ii. The keypad codes were not sufficient.

c. CryoOH was acting as a pick-up station, but did not meet the requirements of a pickup station.

i. The clinic received patient-specific prescriptions from Empower Pharmacy (Florida) and Cedar Pharmacy (Idaho).

ii. CryoOH did not meet the requirements of a pickup station as there was no clear and convincing evidence that delivery of the prescription to the patient would result in danger to the public health or safety or result in danger to the patient, as required by rule to act as a pick-up station.

d. Multi-dose vials were not properly labeled.

i. The following products were observed but the vial did not include a date opened and/or the beyond use date (BUD):

1. Glow 27/5/10 mg/vial - 1 vial

2. NAD + - 1 vial

3. BPC 157/TB 500 - 1 vial

4. Kenalog 50 mg/5 ml - 1 vial

e. Adulterated drugs were comingled in the active drug stock.

i. Expired and adulterated drugs were observed in the active drug stock, including but not limited to:

1. epinephrine 1 mg/ml

2. diphenhydramine 500 mg/10 ml

3. bacteriostatic sodium chloride injection

4. Amino Blend

ii. An Olympia Mineral Blend vial with a BUD of 7/28/2025 from Olympia; however, the clinic’s label stated a 28-day BUD of 8/7/2025. This exceeded the Outsourcer's BUD.

f. The clinic was personally furnishing drugs without a prescriber on-site.

i. Injectable peptides from Alpha BioMed were compounded and personally furnished to patients by nursing staff, instead of by a prescriber.

g. Patient-specific prescriptions were used as office stock.

i. Three different prescriptions were dispensed to Ms. Schell, but intended to be used as office stock, including:

1. NAD+, bacteriostatic water, and a jar of benzocaine/lidocaine/tetracaine ointment.

ii. One prescription was dispensed to a nurse at the clinic, which included:

1. Three total bottles of valacyclovir 1 gm tablet.

iii. Two prescriptions for semaglutide/glycine/cyanocobalamin were dispensed to patients of the clinic but were unboxed and used as office stock.

h. Immediate-use, sterile non-hazardous compounding occurring without the required prescriber oversight.

i. CryoOH advertised IV hydration, but Ms. Schell stated a prescriber was only on-site approximately weekly. It appeared that immediate-use sterile compounding was occurring without the personal supervision or final check by a prescriber.

i. Dispensing of dangerous drugs pursuant to a protocol.

i. Board inspectors observed detailed reconstitution instructions and dose ranges taped to cabinets, as well as a 48-page binder with the title “Infusion Protocols.”

1. It appeared that the clinic operated under protocols, rather than patient-specific orders from a prescriber. The clinic does not meet criteria to administer dangerous drugs via protocol.

5. A request for records was included in the inspection report, #17, which included three years of the following records to be provided to the Board within three business days, pursuant to the Ohio Administrative Code, including:

a. Purchases of any Alpha BioMed product.

b. Personally furnishing records for any Alpha BioMed product.

c. Prescriber orders for the administration of Botox Cosmetic, Dysport, and Alpha BioMed products.

d. Administration records of Botox Cosmetic, Dysport, and Alpha BioMed products.

e. Correspondence with Alpha BioMed on products offered and/or the company's status as a manufacturer/wholesaler (any correspondence, no timeframe).

f. Records of purchase of any dangerous drug (i.e. Botox, Dysport, etc.) from Unboxed Fillers or any other entity.

i. The request was submitted by a Board Specialist again on August 1, 2025, for the records that had not yet been received. As of the issuance of this Notice letter, CryoOH has failed to submit the following records to the Board: patient records of:

1. Prescriber orders for the administration of Botox Cosmetic, Dysport, and Alpha BioMed products.

2. Records of the administration of Botox Cosmetic, Dysport, and Alpha BioMed products.

3. Records of personally furnishing for any Alpha BioMed product.

6. During the July 23, 2025 inspection, CryoOH's owner, Mary Beth Schell, was interviewed by Board inspectors. She stated the following:

a. Botox Cosmetic and Dysport were purchased from Unboxed Fillers, a website offering products she described as the same as Botox Cosmetic but cheaper.

b. Ms. Schell described Botox Cosmetic as half the price compared to purchasing from AbbVie. [Note: Botox is manufactured by Allergan and sold by AbbVie.]

c. Her nurses went shopping for medication inventory. Once the shopping cart contained the needed products, the nurse(s) would contact Ms. Schell to submit payment.

d. Ms. Schell acknowledged she did not have much oversight (over this process) and did not vet out distributors to determine whether they were licensed by the Board.

CONCLUSIONS OF LAW

1. Such conduct as set forth in the Findings of Fact, constitutes a violation of section 3715.52 of the ORC, prohibited acts, each, a misdemeanor of the fourth degree: The following acts and causing them are prohibited:

a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and

d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4); and

e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5); and

f. Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted pursuant to sections 3715.52 to 3715.72 of the Revised Code, ORC Section 3715.52(A)(10).

2. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree.

3. Such conduct as set forth in the Findings of Fact, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular.

4. Such conduct as set forth in the Findings of Fact, each constitutes a violation of Section 4729.60(B) of the ORC, Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale.

5. Such conduct as set forth in the Findings of Fact, constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective May 19, 2025:

a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

[1] ORC Section 3715.63 states: When a drug or device is adulterated
[2] ORC Section 3715.64 states: When a drug or device is misbranded

i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and

ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and

b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

6. Such conduct as set forth in the Findings of Fact, constitutes a violation of section 4729.291(A) of the ORC, Drugs personally furnished by prescriber- Except when provided under section 4731.97 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes.

7. Such conduct as set forth in the Findings of Fact, constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022:

a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and

b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).

8. Such conduct as set forth in Findings of Fact, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements:

a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and

b. A… licensed health professional authorized to prescribe drugs… will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and

c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

9. Such conduct as set forth in Findings of Fact, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023:

   a. Violating any rule of the board, ORC Section 4729.57(B)(2); and

   b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and

   c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and

   d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and

   e. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(B)(6); and

   f. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and

   g. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

10. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022:

    a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and

    b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and

    d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); and

    e. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning

a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and

f. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and

g. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and

h. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).

11. Such conduct as set forth in the Findings of Fact, constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, Non-Hazardous Drugs Compounded by a Prescriber:

    a. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and

    b. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

        i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

        ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and

    c. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

        i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and

        ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and

        iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and

        iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and

        v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and

        vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and

vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and

viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and

ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9); and

d. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and

e. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and

f. All the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and

2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and

3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and

4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and

5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and

6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and

7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4); and

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-03(I)(5); and

g. A prescriber shall not compound drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple

non-patient specific doses are produced in a single activity is prohibited, OAC Rule 4729:7-3-03(J).

12. Such conduct as set forth in the Findings of Fact, constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, Immediate-use, sterile non-hazardous drugs compounded by a prescriber:

    a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

        i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and

        ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and

        iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and

        iv. Ensuring training and competency of compounding personnel, OAC Rule 4729:7-3-04(A)(4); and

        v. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and

        vi. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and

        vii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-04(A)(7); and

        viii. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-04(A)(8); and

    b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

        i. The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device, OAC Rule 4729:7-3-04(B)(1); and

        ii. Personnel shall adhere to appropriate aseptic technique, including all the following:

            1. Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure, OAC Rule 4729:7-3-04(B)(2)(a); and

2. Compounding personnel shall don gloves prior to engaging in compounding activities, OAC Rule 4729:7-3-04(B)(2)(b); and

iii. If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces, OAC Rule 4729:7-3-04(B)(3); and

iv. The beyond-use date for an immediate-use compounded drug preparation is as follows:

1. Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(a); and

2. For preparations of buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(b); and

v. If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely disposed. Records of disposal shall be maintained in accordance with rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(B)(5); and

vi. Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

1. Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name, OAC Rule 4729:7-3-04(B)(6)(a); and

2. The name and quantity of each ingredient, OAC Rule 4729:7-3-04(B)(6)(b); and

3. The beyond-use date and time prepared, OAC Rule 4729:7-3-04(B)(6)(c); and

4. The name or initials of the person who prepared the compounded drug preparation, OAC Rule 4729:7-3-04(B)(6)(d); and

vii. Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber, OAC Rule 4729:7-3-04(B)(7); and

c. Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues.

Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins, OAC Rule 4729:7-3-04(C); and

d. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and

e. Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(H); and

f. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-04(K); and

g. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

   i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and
   ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and

h. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

   i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

   ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and

i. All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

   i. Verify the accuracy of:

      1. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

      2. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and

      3. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and

   ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4); and

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-04(N)(5).

13. Such conduct as set forth in the Findings of Fact, constitutes a violation of Rule 4729:5-3-12 of the OAC, as effective March 1, 2020:

    a. A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs pursuant to a protocol. As used in this rule, "protocol" means a definitive set of written treatment guidelines with orders for drugs and their specified dosages for administration to individuals under the following circumstances:

        i. The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks, OAC Rule 4729:5-3-12(A)(1); and

        ii. The administration of biologicals or vaccines to individuals for the purpose of preventing diseases, OAC Rule 4729:5-3-12(A)(2); and

        iii. The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns, OAC Rule 4729:5-3-12(A)(3); and

        iv. The administration of erythromycin for prevention of ophthalmia neonatorum, OAC Rule 4729:5-3-12(A)(4); and

        v. The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729 of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention, OAC Rule 4729:5-3-12(A)(5).

14. Such conduct as set forth in the Findings of Fact, constitutes a violation of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024: To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration.

15. Such conduct as set forth in Findings of Fact, constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020: All terminal distributors of dangerous drugs shall provide effective controls and procedures to: Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards

to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

16. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, as effective March 1, 2020:

    a. Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1); and

    b. A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (E)(2) of this rule, OAC Rule 4729:5-19-02(F)(1); and

    c. Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug, OAC Rule 4729:5-19-02(K).

17. Such conduct as set forth in Findings of Fact, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021:

    a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and

    b. During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections, OAC Rule 4729:5-19-03(H); and

    c. During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs, OAC Rule 4729:5-19-03(I); and

    d. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and

e. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M).

18. Such conduct as set forth in Findings of Fact, constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective March 1, 2020:

a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and

b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and

c. Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver, OAC Rule 4729:5-19-04(D); and

d. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either:

i. For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug, OAC Rule 4729:5-19-04(E)(1)(a); and

ii. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and

iii. Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification, OAC Rule 4729:5-19-04(E)(3); and

e. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years, OAC Rule 4729:5-19-04(J).

19. Such conduct as set forth in Findings of Fact, constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, as effective December 1, 2020: The state board of pharmacy may restrict a

site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

a. Danger to public health or safety, OAC Rule 4729:5-5-14(C)(1); or

b. Danger to the patient, OAC Rule 4729:5-5-14(C)(1).

DECISION OF THE BOARD

Pursuant to Section 4729.55(E) of the Ohio Revised Code, the Board finds that CryOH and its Owner Mary Beth Schell have violated sections of Chapters 3715. and 4729. of the Ohio Revised Code and multiple rules of the board.

Further, pursuant to Section 4729.57 of the Ohio Revised Code and Ohio Administrative Code Rule 4729:5-1-01(U), and after consideration of the record as a whole, the nature and egregiousness of the findings of fact and violations of law, the Ohio Board of Pharmacy adjudicates the matter of CryoOH DBA: Cryo Ohio Inc. as follows:

On the basis of the Findings of Fact and Section (1) through (6) of the Conclusions of Law, taken collectively or as individual violations, the Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs (TDDD) license, No. 02-60001584, held by CryoOH DBA: Cryo Ohio Inc., effective the date of this Order.

Pursuant to 4729.57 of the Ohio Revised Code, the Ohio Board of Pharmacy imposes a monetary penalty in the amount of $90,000.00. This fine will be attached to the license record for CryoOH DBA: Cryo Ohio Inc. and must be paid no later than 180 days from the effective date of this Order. To pay this fine a representative of CryoOH must log in to www.elicense.ohio.gov and process the items in the cart.

Further, the Board hereby grants the State's Motion to Seal portions of the Record in this matter including, but not limited to, all confidential patient health information contained in the record, specifically State's Exhibit 4.

Ms. Ferris moved for Findings of Fact; Mr. Miller seconded the motion. Motion passed (Yes-5/No-0).

Ms. Ferris moved for Conclusions of Law; Mr. Miller seconded the motion. Motion passed (Yes-5/No-0).

Ms. Ferris moved for Action of the Board; Mr. Miller seconded the motion. Motion passed (Yes-5/No-0).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the

agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin County. Such notices of appeal shall be filed within fifteen (15) days after the service of the notice of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **October 23, 2025**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/alg/jrn

cc: David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov
Kimberly Anderson, State Medical Board of Ohio, at: kimberly.anderson@med.ohio.gov

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 8/6/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE NOS. A-2025-0227**

CryoOH DBA: Cryo Ohio Inc.
3673 Paxton Ave
Cincinnati, OH 45208

License No. 02-60001584

August 6, 2025

Dear CryoOH DBA: Cryo Ohio Inc.:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS CryoOH DBA: Cryo Ohio Inc.'s license as a Terminal Distributor of Dangerous Drugs (TDDD), under authority of Sections 4729.57 and 4729.571 of the Ohio Revised Code.

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to CryoOH DBA: Cryo Ohio Inc.'s method used to possess or distribute dangerous drugs, and the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor. As such, the Board summarily suspends CryoOH DBA: Cryo Ohio Inc.'s license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the ORC.

2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs.

3. Pursuant to Section 4729.571(A)(2) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor.

4. CryoOH DBA: Cryo Ohio Inc., located at 3673 Paxton Ave Cincinnati, Ohio, is a licensed TDDD under license number 02-60001584 and lists Christopher D. Lawley, DO, [Ohio Medical Board license number 34.004502] as the Responsible Person. CryoOH DBA: Cryo Ohio Inc. is owned by Mary Beth Schell.

ALLEGATIONS

1. On or about July 23, 2025 a Board Specialist and Board Agent (Board inspectors) conducted an inspection at CryoOH DBA: Cryo Ohio Inc. (CryoOH), located at 3673 Paxton Ave Cincinnati, Ohio. Mary Beth Schell, CryoOH's owner, who is not a licensed healthcare professional, was present and assisted Board Inspectors during the inspection. At the time of the inspection, CryoOH employed the following healthcare professionals: Christopher D. Lawley, DO; Jonathan W. Van Zile, MD, [Ohio Medical Board license number 35.053908]; Meghan I. Johnson, CRNA [Ohio Board of Nursing license numbers APRN.CRNA.07268 and RN.274865]; Lindsey France, CRNA [Ohio Board of Nursing license numbers APRN.CRNA.0020548 and RN.505468]; and Erin Sedgwick, [Ohio Board of Nursing license number RN.326607].

2. The inspection revealed CryoOH was in possession of illegal dangerous drugs, listed in Allegation 3, purchased from Alpha BioMed and Unboxed Fillers.

    a. Alpha BioMed is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration. Dangerous Drugs purchased from Alpha BioMed are misbranded.

    b. Unboxed Fillers's website states they are a licensed facility in Europe; however, Unboxed Fillers is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration. Dangerous Drugs purchased from Unboxed Fillers are misbranded.

3. CryoOH was in possession of the following illegal drugs during the inspection:

    a. 3 vials of Botox Cosmetic vials with non-English text on the labels

i. 2 vials were used and 1 vial was partially used

1. Botox is manufactured by Allergan and sold by AbbVie. On or about July 24, 2025, after review of the vials, AbbVie confirmed the vials were manufactured- for and distributed to- Turkey. While the product was authentic, it was not purchased through a legal supply chain and was not approved by the U.S. Food and Drug Administration (FDA). It was illegal in the United States.

b. 2 vials of Dysport with non-English text on the labels

i. 1 vial was unused vial and 1 vial was partially used

1. Dysport is manufactured by Ipsen. On or about July 31, 2025, after review of the vials, Ipsen confirmed the vials were diverted product and not purchased from a legal supply chain. The vials were originally distributed to Turkey. The product was authentic; however, it was not approved by the FDA and was illegal to purchase and possess in the United States.

c. 10 vials of injectable products from Alpha BioMed, including:

i. 5 vials of BPC-157/TB 500 10 mg/10 mg/vial

1. 4 vials were unused and 1 vial was partially used

ii. 3 vials of GLOW (GHK-CU/BPC 157/TB 500) 27/5/10 mg/vial

1. 2 vials were unused and 1 vial was partially used

iii. 2 vials of NAD+ Biofermented 1000 mg/vial

1. 1 vial was unused and 1 vial was partially used

4. The inspection conducted on July 23, 2025, resulted in seven warnings requiring written responses and two warnings, including but not limited to:

a. Purchased dangerous drugs from unlicensed entities.

i. Board inspectors observed vials of injectable drugs from unlicensed entities, Alpha BioMed and Unboxed Fillers.

ii. The clinic did not complete a query of the board's online roster prior to purchase of dangerous drugs at wholesale.

b. Non-controlled dangerous drugs and hypodermics were not maintained under appropriate supervision and control.

i. Dangerous drugs and hypodermics were stored in the clinic's medication room which was accessible by two doors with keypad locks. During the inspection, one door was open to a second room where patients may receive treatment.

ii. The keypad codes were not sufficient.

c. CryoOH was acting as a pick-up station, but did not meet the requirements of a pickup station.

i. The clinic received patient-specific prescriptions from Empower Pharmacy (Florida) and Cedar Pharmacy (Idaho).

ii. CryoOH did not meet the requirements of a pickup station as there was no clear and convincing evidence that delivery of the prescription to the patient would result in danger to the public health or safety or result in danger to the patient, as required by rule to act as a pick-up station.

d. Multi-dose vials were not properly labeled.

i. The following products were observed but the vial did not include a date opened and/or the beyond use date (BUD):

1. Glow 27/5/10 mg/vial - 1 vial

2. NAD + - 1 vial

3. BPC 157/TB 500 - 1 vial

4. Kenalog 50 mg/5 ml - 1 vial

e. Adulterated drugs were comingled in the active drug stock.

i. Expired and adulterated drugs were observed in the active drug stock, including but not limited to:

1. epinephrine 1 mg/ml

2. diphenhydramine 500 mg/10 ml

3. bacteriostatic sodium chloride injection

4. Amino Blend

ii. An Olympia Mineral Blend vial with a BUD of 7/28/2025 from Olympia; however, the clinic’s label stated a 28-day BUD of 8/7/2025. This exceeded the Outsourcer's BUD.

f. The clinic was personally furnishing drugs without a prescriber on-site.

   i. Injectable peptides from Alpha BioMed were compounded and personally furnished to patients by nursing staff, instead of by a prescriber.

g. Patient-specific prescriptions were used as office stock.

   i. Three different prescriptions were dispensed to Ms. Schell, but intended to be used as office stock, including:

      1. NAD+, bacteriostatic water, and a jar of benzocaine/lidocaine/tetracaine ointment.

   ii. One prescription was dispensed to a nurse at the clinic, which included:

      1. Three total bottles of valacyclovir 1 gm tablet.

   iii. Two prescriptions for semaglutide/glycine/cyanocobalamin were dispensed to patients of the clinic but were unboxed and used as office stock.

h. Immediate-use, sterile non-hazardous compounding occurring without the required prescriber oversight.

   i. CryoOH advertised IV hydration, but Ms. Schell stated a prescriber was only on-site approximately weekly. It appeared that immediate-use sterile compounding was occurring without the personal supervision or final check by a prescriber.

i. Dispensing of dangerous drugs pursuant to a protocol.

   i. Board inspectors observed detailed reconstitution instructions and dose ranges taped to cabinets, as well as a 48-page binder with the title “Infusion Protocols.”

      1. It appeared that the clinic operated under protocols, rather than patient-specific orders from a prescriber. The clinic does not meet criteria to administer dangerous drugs via protocol.

5. A request for records was included in the inspection report, #17, which included three years of the following records to be provided to the Board within three business days, pursuant to the Ohio Administrative Code, including:

   a. Purchases of any Alpha BioMed product.

   b. Personally furnishing records for any Alpha BioMed product.

c. Prescriber orders for the administration of Botox Cosmetic, Dysport, and Alpha BioMed products.

d. Administration records of Botox Cosmetic, Dysport, and Alpha BioMed products.

e. Correspondence with Alpha BioMed on products offered and/or the company's status as a manufacturer/wholesaler (any correspondence, no timeframe).

f. Records of purchase of any dangerous drug (i.e. Botox, Dysport, etc.) from Unboxed Fillers or any other entity.

i. The request was submitted by a Board Specialist again on August 1, 2025, for the records that had not yet been received. As of the issuance of this Notice letter, CryoOH has failed to submit the following records to the Board: patient records of:

1. Prescriber orders for the administration of Botox Cosmetic, Dysport, and Alpha BioMed products.

2. Records of the administration of Botox Cosmetic, Dysport, and Alpha BioMed products.

3. Records of personally furnishing for any Alpha BioMed product.

6. During the July 23, 2025 inspection, CryoOH's owner, Mary Beth Schell, was interviewed by Board inspectors. She stated the following:

a. Botox Cosmetic and Dysport were purchased from Unboxed Fillers, a website offering products she described as the same as Botox Cosmetic but cheaper.

b. Ms. Schell described Botox Cosmetic as half the price compared to purchasing from AbbVie. [Note: Botox is manufactured by Allergan and sold by AbbVie.]

c. Her nurses went shopping for medication inventory. Once the shopping cart contained the needed products, the nurse(s) would contact Ms. Schell to submit payment.

d. Ms. Schell acknowledged she did not have much oversight (over this process) and did not vet out distributors to determine whether they were licensed by the Board.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52 of the ORC, prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization: The following acts and causing them are prohibited:

a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and/or

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and/or

d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4); and/or

e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5); and/or

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[1] ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. ***
5. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
6. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:
a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

f. Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted pursuant to sections 3715.52 to 3715.72 of the Revised Code, ORC Section 3715.52(A)(10).

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective May 19, 2025, each violation punishable by a maximum penalty of $1,000:

   a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

      i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

      ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or

   b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

6. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.291(A) of the ORC, Drugs personally furnished by prescriber- Except when provided under section 4731.97 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of $1,000:

    a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or

    b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).

8. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements, each violation punishable by a maximum penalty of $1,000:

    a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or

    b. A… licensed health professional authorized to prescribe drugs… will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or

    c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

9. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of $1,000:

a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or

b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or

c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or

d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or

e. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(B)(6); and/or

f. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or

g. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

10. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of $1,000:

a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or

c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or

d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); and/or

e. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or

f. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or

g. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and/or

h. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).

11. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, Non-Hazardous Drugs Compounded by a Prescriber, each violation punishable by a maximum penalty of $1,000:

a. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and/or

b. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and/or

c. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and/or

iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and/or

iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and/or

v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and/or

vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and/or

vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and/or

viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and/or

ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9); and/or

d. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and/or

e. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and/or

f. All the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and/or
2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and/or
3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and/or
4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and/or
5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and/or
6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and/or
7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4); and/or

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-03(I)(5); and/or

g. A prescriber shall not compound drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited, OAC Rule 4729:7-3-03(J).

12. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, Immediate-use, sterile non-hazardous drugs compounded by a prescriber, each violation punishable by a maximum penalty of $1,000:

a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and/or

iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and/or

iv. Ensuring training and competency of compounding personnel, OAC Rule 4729:7-3-04(A)(4); and/or

v. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and/or

vi. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and/or

vii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-04(A)(7); and/or

viii. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-04(A)(8); and/or

b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

i. The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile, non-hazardous drugs from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device, OAC Rule 4729:7-3-04(B)(1); and/or

ii. Personnel shall adhere to appropriate aseptic technique, including all the following:

1. Before beginning compounding activities, personnel shall perform a thorough hand-hygiene procedure, OAC Rule 4729:7-3-04(B)(2)(a); and

2. Compounding personnel shall don gloves prior to engaging in compounding activities, OAC Rule 4729:7-3-04(B)(2)(b); and/or

iii. If not immediately administered, the finished compounded drug preparation shall be regularly monitored by compounding personnel to minimize the potential for contact

with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other compounded drug preparations, and direct contact of outside surfaces, OAC Rule 4729:7-3-04(B)(3); and/or

iv. The beyond-use date for an immediate-use compounded drug preparation is as follows:

1. Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(a); and/or

2. For preparations of buffered lidocaine containing antimicrobial preservatives, no later than twelve-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(b); and/or

v. If administration has not begun within the beyond-use dating described in paragraph (B)(4) of this rule, the drug shall be promptly, properly, and safely disposed. Records of disposal shall be maintained in accordance with rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(B)(5); and/or

vi. Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

1. Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name, OAC Rule 4729:7-3-04(B)(6)(a); and/or

2. The name and quantity of each ingredient, OAC Rule 4729:7-3-04(B)(6)(b); and/or

3. The beyond-use date and time prepared, OAC Rule 4729:7-3-04(B)(6)(c); and/or

4. The name or initials of the person who prepared the compounded drug preparation, OAC Rule 4729:7-3-04(B)(6)(d); and/or

vii. Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber, OAC Rule 4729:7-3-04(B)(7); and/or

c. Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free

disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins, OAC Rule 4729:7-3-04(C); and/or

d. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and/or

e. Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(H); and/or

f. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-04(K); and/or

g. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

    i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and

    ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and/or

h. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

    i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

    ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and/or

i. All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

    i. Verify the accuracy of:

        1. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

        2. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and/or

        3. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4); and/or

iii. A licensed prescriber is on-site and immediately available, OAC Rule 4729:7-3-04(N)(5).

13. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-3-12 of the OAC, as effective March 1, 2020, Protocols for medication administration, each violation punishable by a maximum penalty of $1,000:

a. A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs pursuant to a protocol. As used in this rule, "protocol" means a definitive set of written treatment guidelines with orders for drugs and their specified dosages for administration to individuals under the following circumstances:

i. The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the revised code to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks, OAC Rule 4729:5-3-12(A)(1); and/or

ii. The administration of biologicals or vaccines to individuals for the purpose of preventing diseases, OAC Rule 4729:5-3-12(A)(2); and/or

iii. The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns, OAC Rule 4729:5-3-12(A)(3); and/or

iv. The administration of erythromycin for prevention of ophthalmia neonatorum, OAC Rule 4729:5-3-12(A)(4); and/or

v. The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in agency 4729 of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention, OAC Rule 4729:5-3-12(A)(5).

14. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, each violation punishable by a maximum penalty of $1,000: To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration.

15. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to: Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

16. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

    a. Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1); and/or

    b. A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (E)(2) of this rule, OAC Rule 4729:5-19-02(F)(1); and/or

    c. Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug, OAC Rule 4729:5-19-02(K).

17. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021, each violation punishable by a maximum penalty of $1,000:

    a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and/or

    b. During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections, OAC Rule 4729:5-19-03(H); and/or

    c. During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-

controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs, OAC Rule 4729:5-19-03(I); and/or

d. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and/or

e. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M).

18. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and/or

b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or

c. Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver, OAC Rule 4729:5-19-04(D); and/or

d. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either:

i. For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug, OAC Rule 4729:5-19-04(E)(1)(a); and/or

ii. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and/or

iii. Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification, OAC Rule 4729:5-19-04(E)(3); and/or

e. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years, OAC Rule 4729:5-19-04(J).

19. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, as effective December 1, 2020, each violation punishable by a maximum penalty of $1,000: The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

    a. Danger to public health or safety, OAC Rule 4729:5-5-14(C)(1); or

    b. Danger to the patient, OAC Rule 4729:5-5-14(C)(1).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/alg/jrn

cc: David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov
Melinda Snyder, State Medical Board of Ohio, at: Melinda.Snyder@med.ohio.gov